Uses of Genomic Tools in Programs Administered by the Agricultural Marketing Service USDA Listening Session December 6, 2005 American Berkshire Association Testimony

The American Berkshire Association (ABA) appreciates the opportunity to submit this testimony on behalf of its breeder members. Organized in 1875, the ABA is the oldest swine breed registry in the United States. USDA has had a long-standing policy in several departments to follow the Breed Claims of the numerous Pure Breed Registries. Currently the ABA Breed Claims, October, 2004, are used to verify Berkshire breed ancestry. The USDA policy was confirmed by administrators in AMS as well as USDA Under Secretary William Hawks.

The ABA has had the unique experiences of losing a premium pork export program due to unacceptable verification, regularly using genomic tools (DNA tests for HAL 1843* and Rendement Napole genotypes), and developing a certification program to meet Japanese export standards of 100% Berkshire. Concerns about USDA use of genomic tools in certification programs are in two areas, Enforcement and Scientific Accuracy.

Enforcement

The true purpose of any certification program is to increase customer confidence by auditing the product and production system to its product claims, allowing only 'certified' product to be labeled. Premium prices for products that meet their claims are usually the desired result of certification. This means some product will be disqualified for not meeting claims. Disqualified producers will not receive premium prices and may well take legal action against the certifier to recover their lost income. For this reason any rules or methods of certification must have a legal framework that withstands challenges.

The ABA pedigree certification programs require each breeder to personally sign each application for animal registry. By this signature each breeder warrants that the animals are of the ancestry shown on the pedigree application and agrees to comply with the rules of the ABA. There is a due process, shown in the Breed Claims, that requires the breeder to cooperate with any ABA investigation initiated by a complaint against the breeder. The genomic tool of parentage determination may be used to validate ancestry in dispute. Parentage determination is based on similarity of parent-offspring genomes and is quite accurate for that purpose.

Unfortunately parentage determination is not useful for discriminating between breeds. Over the decades several breeders have been found guilty of improper pedigrees, resulting in cancellation of animal pedigrees and permanent loss of breeder privileges. The ABA rules allow Breed representatives to inspect any herd at any time, respecting

bio-security concerns. The Breed Claims based on the auditable rules of the ABA have a legal framework.

Genotype evaluation tests are usually licensed to private companies. Some companies make the tests available to the public for a fee while other companies choose to keep the tests proprietary as a competitive marketing advantage. How will USDA assure all breeders that certification genomic tools are publicly available at a reasonable price?

Berkshire breeders have used genomic tools since they became publicly available in 1991. In 1991, the test for HAL 1843* genotype (Fujii et al, 1991) became available. In 2000, a test for Rendement Napole genotype (LeRoy et al, 1990) became available. Animals with mutant genes at either site produce substandard pork quality. Berkshire breeders desire to use only breeding stock with the non-mutant genotypes. Five US laboratories were licensed to do the HAL 1843* evaluation, three continue to do the test. Only one US laboratory is licensed to do the Rendement Napole evaluation.

Genomic laboratories rarely take any responsibility for the results of their tests. Berkshire breeders, and other swine breeders using these tests, find some incorrectly reported genotypes when they genotype progeny animals. Some breeders have suffered considerable financial losses when an incorrectly evaluated sire (usually reported non-mutant but having one or two mutant genes) was used in an artificial insemination stud.

The Terms and Conditions of GENESEEK, INC, a reputable company used by many breeders, are shown in Appendix A. The warranty disclaimer is excerpted here: "Warranty or Representation Disclaimers. GENESEEK DISCLAIMS AND EXCLUDES ALL WARRANTIES OR REPRESENTATION OF ANY KIND, EITHER EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO ITS SERVICES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHTS, OR WARRANTIES ARISING BY COURSE OF DEALINGS OR CUSTOM OF TRADE. YOU HEREBY EXPRESSLY UNDERSTAND THAT THE TESTING SERVICES PROVIDED HEREUNDER HAVE AN INHERENT POTENTIAL FOR ERROR AND THAT GENESEEK MAKES NO REPRESENTATION THAT ITS TESTING SERVICES WILL BE ACCURATE, COMPLETE, OR ERROR-FREE." Other firms providing genomic tools have similar disclaimers of test fitness and accuracy.

If the USDA-AMS decides to accept genomic tools, will it also accept the legal liability for incorrect genotype results that genomic laboratories will not accept? It is very difficult to imagine a legal framework that would allow product disqualification based on genomic tests that have no warranty of accuracy. If all products 'pass' the genomic tests the resulting certification program has no value.

Scientific Accuracy

The Berkshire breed is the oldest swine breed, being recognized as a breed in England in the early 1800's. Some authorities suggest that Berkshires were used as a parent breed for all other British breeds and the Pietrain (Jones, 1998). The ABA pedigree registry started in 1875 and has remained open only to Berkshires recorded by the English Berkshire and Canadian Berkshire registries. Purebred Berkshire pork ranks superior in eating quality evaluations against other US breeds (Goodwin, 2004, see Appendix B).

There are 50,000-100,000 gene loci in the pig and multiple alleles at some loci (Moran, 1998). Some of these loci may be linked with varying recombination frequencies. Given the parent relationship that Berkshires have with British and US breeds, many loci from a large sample of each breed must be evaluated for differences in gene frequencies in any attempt to find informative genomic tools. University of Nebraska Geneticist Dr. Rodger Johnson has further developed some concerns about the amount of background research and probability of success when discriminating between breeds (see attached paper). Who will fund a research project of this scope? Who would make the final determination of each breed's genetic marker 'profile'? Who would assume liability to defend this genetic 'profile'?

International premium pork markets require 100% purebred Berkshire market animals. Purebred animals are much more costly to produce than crossbreds (Johnson, 1980). Closed pedigree breeds' inbreeding levels continually increase, further reducing reproductive and growth performance, resulting in greater costs of purebred pig production (Ferraz et al, 1993). Producers that can get inferior meat quality crossbred animals 'certified' through poorly designed genotype evaluations can reap much larger profits than purebred producers while reducing reputation and demand for the purebred Berkshire products. How will genomic tools be designed to discriminate between purebred and crossbred Berkshire market pigs?

There are several Breed organizations of different species that have dedicated countless hours and dollars to maintaining the requirements of their specific breed. These efforts have included specific definition and enforcement of several factors including individual animal identification, specific animal genetics and phenotype. How will USDA develop and propose genomic identification rules for all these breeding animals?

Will USDA determine the phenotype within a breed? It is unlikely that any genetic marker will be associated with only one breed. Producers could screen animals of other breeds for the few that have the desired marker. A population of 'USDA Certified' animals could be assembled that had no ancestry of the desired breed.

If gene frequencies are used to classify breeds how will USDA account for the genetic change in frequencies over time that will occur due to selection and random drift?

Conclusions

The ABA has decided to develop and promote an auditable certification program for 100% Berkshire pork based upon pedigree verification and supplemented with genomic evaluation of sires for HAL 1843* and Rendement Napole genotypes. Genomic tests of parentage may be used to verify pedigree integrity as needed. We strongly support a USDA-AMS Process Verified Program based upon the established Berkshire Breed Claims. Trade missions to Japan in recent years, in cooperation with the Foreign Agricultural Service, have shown great consumer acceptance of an auditable program supervised by USDA.

Simple 'quick' genomic tools without any hope of legal defense must be avoided. Nearly two centuries of Berkshire breeders' efforts could quickly be destroyed by USDA endorsement of such genomic tools. Neither producers nor consumers are protected by such a USDA endorsement. Why would USDA take the premiums resulting from nearly 200 years of Berkshire breeders' efforts and award them to the owners of such genomic tools?

References

- Ferraz, J.B.S., R.N. Goodwin and R.K. Johnson. 1993. Inbreeding in the Berkshire and Poland China breeds. Journal of Animal Science 71(Suppl 1):36.
- Fujii, J., K. Otsu, F. Zorzato, S. DeLeon, V. K. Khanna, J. E. Weiler, P. J. O'Brien and D.H. MacLennon. 1991. Identification of a mutation in the porcine ryanodine
 - receptor associated with malignant hyperthermia. Science 253:448-451.
- Goodwin, R.N. 2004. National Barrow Show Pork Quality Trends. In: Proceedings of the 2004 National Swine Improvement Federation Annual Meeting, Des Moines, IA.
- Johnson, R.K.1980. Heterosis and breed effects in swine. North Central Regional Publication No. 262. University of Nebraska, Lincoln, NE.
- Jones, G.F. 1998. Genetic Aspects of Domestication, Common Breeds and their Origin. In: The Genetics Of The Pig. pp 33-36. M. F. Rothschild and A. Ruvinsky, editors. CAB International, New York, NY.
- LeRoy, P., J. Naveau, J. M. Elsen and P. Sellier. 1990. Evidence for a new major gene influencing meat quality in pigs. Genet. Res. 55:33-40.

Moran, C. 1998. Molecular Genetics. In: The Genetics Of The Pig. pp 154. M. F. Rothschild and A. Ruvinsky, editors. CAB International, New York, NY.

Appendix A

GENESEEK Inc Terms and Conditions - See Attached

Appendix B

(Taken from National Barrow Show Pork Quality Trends, Goodwin, 2004) Berkshire pork loin eating quality results from the 1996-2004 National Barrow Show Sire Progeny Tests are shown in Table 1. Berkshire breeders enter the most sire groups in each annual test. The longissimus sections from the eleventh and twelfth ribs were delivered to the Iowa State University Food Science Laboratory. Both sections from each longissimus sample were broiled simultaneously to 71°C in an electric oven broiler (210°C). Temperature of each section was individually monitored using thermocouples attached to an Omega digital thermometer. A trained sensory panel evaluated cooked eleventh rib sections for juiciness (JUICY) and tenderness (TENDER), using a score of 1 to 10. A rating of 1 represented a dry, tough section. A rating of 10 represented a juicy, tender section. Sensory analysis testing involved the use of at least a four-member, highly trained professional sensory panel. Panel member size was restricted because only a limited number of adequately sized cubes could be removed from one section. Training consisted of approximately 20 hours spent presenting the panelists with commercial loin samples that display maximum and minimum intensities of juiciness and tenderness and monitoring individual panelist performance. In this project, the broiled loin section used for sensory analysis was cut such that 4 or more 1.3 cm cubes were removed from the center of the section. Each panelist was presented with 2 cubes for evaluation of juiciness and tenderness. The second broiled twelfth rib section was evaluated for instrumental texture using a star probe attached to an Instron Universal Testing Machine. Tenderness (INSTRON) was evaluated by an Instron Universal Testing Machine as pressure, in kg, required to compress the cooked section. A higher pressure indicates a less tender section. The star probe attachment was used to determine the amount of force needed to compress the section to 80% of the section height. Cooking loss (CLOSS) was measured by weighing 11th and 12th rib sections before and after broiling to 71 C. Cooking loss is reported as percent loss (broiled weight/raw weight *100) (Goodwin, 2004).

Moran, C. 1998. Molecular Genetics. In: The Genetics Of The Pig. pp 154. M. F. Rothschild and A. Ruvinsky, editors. CAB International, New York, NY.

Appendix A

GENESEEK Inc Terms and Conditions - See Attached

Appendix B

(Taken from National Barrow Show Pork Quality Trends, Goodwin, 2004) Berkshire pork loin eating quality results from the 1996-2004 National Barrow Show Sire Progeny Tests are shown in Table 1. Berkshire breeders enter the most sire groups in each annual test. The longissimus sections from the eleventh and twelfth ribs were delivered to the Iowa State University Food Science Laboratory. Both sections from each longissimus sample were broiled simultaneously to 71°C in an electric oven broiler (210°C). Temperature of each section was individually monitored using thermocouples attached to an Omega digital thermometer. A trained sensory panel evaluated cooked eleventh rib sections for juiciness (JUICY) and tenderness (TENDER), using a score of 1 to 10. A rating of 1 represented a dry, tough section. A rating of 10 represented a juicy, tender section. Sensory analysis testing involved the use of at least a four-member, highly trained professional sensory panel. Panel member size was restricted because only a limited number of adequately sized cubes could be removed from one section. Training consisted of approximately 20 hours spent presenting the panelists with commercial loin samples that display maximum and minimum intensities of juiciness and tenderness and monitoring individual panelist performance. In this project, the broiled loin section used for sensory analysis was cut such that 4 or more 1.3 cm cubes were removed from the center of the section. Each panelist was presented with 2 cubes for evaluation of juiciness and tenderness. The second broiled twelfth rib section was evaluated for instrumental texture using a star probe attached to an Instron Universal Testing Machine. Tenderness (INSTRON) was evaluated by an Instron Universal Testing Machine as pressure, in kg, required to compress the cooked section. A higher pressure indicates a less tender section. The star probe attachment was used to determine the amount of force needed to compress the section to 80% of the section height. Cooking loss (CLOSS) was measured by weighing 11th and 12th rib sections before and after broiling to 71 C. Cooking loss is reported as percent loss (broiled weight/raw weight *100) (Goodwin, 2004).

GENESEEK, INC. TERMS AND CONDITIONS

These terms and conditions contained herein govern the order of testing services from GeneSeek, Inc. ("GENESEEK") and any customer (hereinafter referred to as "You").

- 1. Acknowledgment and Acceptance. Please read the following terms of the agreement carefully, by completing the order form, YOU hereby agree to all of the terms and conditions set forth in the order form, including all warranty disclaimers and limitations of liability. ACCEPTANCE OF SERVICES SHALL BE DEEMED AGREEMENT TO THESE TERMS AND CONDITIONS. NO DOCUMENT ISSUED BY YOU ATTEMPTING TO NEGATE OR OTHERWISE MODIFY THE TERMS HEREOF, INCLUDING ANY PURCHASE ORDER OR REQUEST FOR PROPOSAL, SHALL BE BINDING UPON GENESEEK, AND INSTEAD THE FOREGOING TERMS AND CONDITIONS SHALL EXCLUSIVELY GOVERN THE PROVISION OF SERVICES TO YOU BY GENESEEK.
- 2. <u>Provision of Services</u>. GENESEEK provides testing services in accordance with the specifics of those tests selected on the order form. If, after delivery and inspection, YOU determine that the services do not conform to the tests YOU selected and are, therefore, unacceptable, please notify us immediately. GENESEEK will either re-perform the services, or issue a credit therefore, at our option.
- 3. Warranty or Representation Disclaimers. GENESEEK DISCLAIMS AND EXCLUDES ALL WARRANTIES OR REPRESENTATION OF ANY KIND, EITHER EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO ITS SERVICES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHTS, OR WARRANTIES ARISING BY COURSE OF DEALINGS OR CUSTOM OF TRADE. YOU HEREBY EXPRESSLY UNDERSTAND THAT THE TESTING SERVICES PROVIDED HEREUNDER HAVE AN INHERENT POTENTIAL FOR ERROR AND THAT GENESEEK MAKES NO REPRESENTATION THAT ITS TESTING SERVICES WILL BE ACCURATE, COMPLETE, OR ERROR-FREE.
- 4. <u>Limitation of Liability</u>. EXCEPT AS AFOREMENTIONED, GENESEEK WILL NOT BE LIABLE FOR ANY CAUSES OF ACTION OR DAMAGES WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY, INCLUDING ANY INDIRECT, CONSEQUENTIAL (INCLUDING LOST PROFITS AND LOST BUSINESS OPPORTUNITIES), SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, ARISING OUT OF THE PERFORMANCE OF SERVICES EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. INCLUDED WITHIN THE SCOPE OF THIS LIMITATION OF LIABILITY ARE DAMAGES ARISING FROM THE ACTS OR NEGLIGENCE ON THE PART OF GENESEEK, ITS AGENTS OR EMPLOYEES IN PERFORMING ITS SERVICES. YOU AGREE THAT GENESEEK'S CUMULATIVE LIABILITY FOR THE SERVICES PERFORMED WILL NOT EXCEED THE AMOUNT PAID BY YOU FOR THOSE SERVICES. THE REMEDIES SET FORTH HEREIN CONSTITUTE YOUR EXCLUSIVE REMEDIES AGAINST GENESEEK FOR SERVICES PERFORMED.
- 5. <u>Customer Representations and Warranties.</u> You hereby represent and warrant that (1) any testing samples will be or are properly taken and collected, (2) that any such samples will be or are properly recorded or labeled, and (3) that any such samples will be or are handled, shipped and packaged appropriately. You are responsible for taking all precautions you believe necessary or advisable to protect any sample sent to GENESEEK against damage, loss or hazard.
- 6. <u>Indemnity</u>. You agree to defend, indemnify, save and hold GENESEEK and its subsidiaries, affiliates, related entities, principals, partners, agents, officers, directors, employees, attorneys, heirs, successors and assigns and each of them harmless from and against any and all claims, actions, demands, losses, damages, judgments, settlements, costs and expenses (including reasonable attorneys' fees, expert fees and other reasonable costs of litigation) and liabilities of any kind and character whatsoever, which may arise by reason of: 1) any act or omission of GENESEEK or any of its officers, directors, employees, or agents in their capacity as officers, directors, employees or agents of GENESEEK in providing services hereunder, and/or 2) the inaccuracy or breach of any of the covenants, promises, representations or warranties made by GENESEEK under this Agreement. The indemnity under this paragraph shall require the payment of costs and expenses by you as they are incurred by GENESEEK.
- 7. <u>Limits of Testing Services</u>. You agree that the testing services provided by GENESEEK are not intended for use in human or clinical diagnostics but are for informational purposes only.
- 8. <u>Entire Agreement.</u> These terms and conditions form an appendix to the primary agreement (AGREEMENT) between GENESEEK and You applicable to GENESEEK's services. These terms and conditions may not be amended or supplemented by You without GENESEEK's prior written consent.
- 9. Severability. If any of the provisions of these terms and conditions shall be held by a court of competent jurisdiction to be contrary to law, the remaining provisions for this Agreement shall remain in full force and effect to the fullest extent of the law.
- 10. <u>Successors and Assigns</u>. These terms and conditions shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, legatees, devisees, personal representatives, successors and assigns.
- 11. Waiver. The failure of any party to seek redress for violation of or to insist upon the strict performance of any term or condition shall in no way be considered a waiver of such term or condition or any rights thereunder or in any way affect the party's right to later enforce or exercise the same or other provisions or rights granted hereunder.
- 12. <u>Survival.</u> The provisions of Sections 5 and 6 of these terms and conditions shall survive the completion and payment of the services provided hereunder.
- 13. Governing Law. The terms and conditions hereunder shall be governed by the laws of the State of Nebraska, without giving effect to its principles of conflicts of law, and the parties hereby irrevocably commit to the jurisdiction and venue of the courts of Nebraska to adjudicate any dispute arising hereunder or relating hereto.